

REMARKS

Claims 1-16, 20-30, 32-38 and 40-42 remain pending in the application, of which claims 1, 20, 28-30 and 33 are currently amended. Claims 17-19 have been cancelled and claims 41 and 42 have been newly added. Based on the foregoing amendments and following remarks, reconsideration and allowance of the application is respectfully requested.

Information Disclosure Statement

A supplemental information disclosure statement including the prosecution history, namely office actions and responses, of related US Patent Application S.N. 10/694,927 is submitted herewith. Applicant respectfully requests consideration of the references cited in the information disclosure statement.

Claim objection – 35 U.S.C. §112

Claim 33 has been amended to remove the shape memory alloy limitation. In view of this amendment, Applicant respectfully requests withdrawal of the §112 objection.

Claim rejections – 35 U.S.C. §102 (e)

Claims 1, 2, 4-6, 7, 10, 11, 14-16, 21, 30 and 40 stand rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Patent Publication No. 2004/0098028 (Martinez). Applicant respectfully disagrees. In order to sustain a rejection under § 102(e), the respective reference must disclose each and every element of the claim, either expressly or inherently. Applicant respectfully submits that Martinez cannot support the § 102(e) rejection because it does not disclose each and every element of the rejected claims, as amended.

Independent claims 1, 30, and 40 each have been amended to recite an active element (claims 1 and 40) or hydrogel member (claim 30) carried entirely within the lumen defined by a vaso-occlusive member, the active element or hydrogel contracts to a deployed configuration that causes the occlusive member to substantially retain its shape (claims 1 and 30) or to stiffen (claim 40) when deployed in a body cavity (claims 1 and 40) or vasculature (claims 30). In contrast, Martinez discloses a vaso-occlusive device comprising three coaxially arranged elements, wherein the intermediate element is configured to expand and protrude through the gaps of the outer element to minimize friction with a delivery catheter, enhance pushability, trackability and increase flexibility of the device when deployed through the catheter (Paragraphs 12 and 13). Martinez does not disclose or suggest an active element that contracts causing the occlusive device to retain its shape or stiffen when deployed. In fact, it is essential to Martinez that its active element expands, thus achieving its intended purpose of minimizing friction and enhancing pushability and flexibility of the device in relationship with the delivery catheter.

For at least these reasons, independent claims 1, 30, and 40, as well as dependent claims 2, 4-6, 7, 10, 11, 14-16, 21, are believed patentable over Martinez.

Claim rejections – 35 U.S.C. §102 (b)

Claims 1 and 20 stand rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Patent No. 6,231,588 (Zadno-Azizi). Applicant respectfully disagrees, since Zadno-Azizi does not disclose each and every element of the rejected claims, as amended.

Independent claim 1 recites “an active element having a pre-deployment configuration carried entirely within the lumen with no portion of the pre-deployed active

element located outside of the lumen, wherein the active element is configured to contract to a deployed configuration without application of a mechanical force when placed in a body.

In contrast, Zadno-Azizi discloses an angioplasty and occlusion catheter, wherein the occlusion element 114 maybe self-expanding (deployed by retracting a sheath that surrounds the catheter) or non-self-expanding (deployed by retracting a pull wire that passes through the catheter); the "catheter 110 has a self-expanding, mechanically deployed occlusion element 114", and again disclosing: "the mechanically deployed occlusion element preferably includes an expansion member 130 surrounded by a membrane 134" (Col. 4 lines 3-9, lines 14-17, lines 36-41). Zadno-Azizi does not disclose or suggest an active element that contracts without application of mechanical force to cause the occlusive device to retain its shape or stiffen when deployed, it rather expands by mechanical force.

Furthermore, the expansion member 130 of Zadno-Azizi is considered by the office action as the claimed active element; however, the expansion member 130 is not carried entirely within the lumen, rather it is secured to the outside of the catheter in its pre-deployed configuration. (Col 6, lines 25-35, Figs. 4B and 5)

For at least these reasons, independent claims 1, as well as dependent claim 20 are believed patentable over Zadno-Azizi.

Claim Rejections - 35 U.S.C. §103

Claims 1-3, 27, 32-35, 38 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Martinez in view of U.S. Patent No. 7,066,904 (Rosenthal). Claims 8, 9, 22-26, 28 and 29 stand rejected under 35 U.S.C. §103(a) as allegedly being

unpatentable over Martinez in view of US Pub No. 2001/0046518 ("Sawhney"). Claims 35-38 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Martinez in view of Rosenthal, and as applied to claim 32 in further view Sawhney.

Applicant respectfully traverses, since each of the claim rejections under §103 are based at least in part on Martinez. As discussed above, Martinez does not disclose an active element having a pre-deployment configuration carried entirely within a lumen, i.e., with no portion of the pre-deployed active element located outside of the lumen, and is configured to contract (claim 1) or to radially contract (claim 32) to a deployed configuration without application of a mechanical force when to thereby cause the occlusive member to substantially retain its shape when deployed in a body cavity (claim 1) or vasculature site (claim 32). Neither Rosenthal nor Sawhney supply these missing features of the claims.

Rosenthal discloses a balloon catheter comprising a hydrogel coating on its outer surface; the hydrogel carries a drug that is released from the hydrogel in a body when the hydrogel is exposed to a triggering agent, which makes the hydrogel to contract and the drug to be squeezed out of the contracted hydrogel. (Col 1, line 47 to Col 2 line 57, Col 6, lines 55-64, Fig 4). Sawhney discloses methods for hydrating (expanding) hydrogel in situ, which releases therapeutic agents to a body to promote sealing or augmentation of tissue or vessels (Paragraphs 22, 26, 104)

For a combination of prior art references to render a claim obvious, the resulting prior art device or method must include all of the limitations of that claim (MPEP §2143). There is nothing in Rosenthal or Sawhney that disclose or suggest that their combination with Martinez will produce an occlusive device with an active element that contract to

cause the occlusive member to substantially retain its shape when deployed in a body cavity or vasculature site. Even if a person skilled in the art would consider modifying the device of Martinez to comprise an active element that contracts according to Rosenthal, the resulting device would be of a contracting active element for drug delivery and not for retaining the shape of the device, absent hindsight in view of the present application.

Furthermore, such combination will teach away from the disclosure of Martinez, where the expanding active element enhances pushability, trackability and increases flexibility of the device when deployed through the catheter (Paragraphs 12 and 13). Having the active element of Martinez to contract would teach away from its intended propose, since the contraction of the active element of Martinez will not minimize friction, enhance pushability, trackability and increases flexibility of the device with the delivery catheter.

Claims 2-3, 8, 9 and 22-29 incorporate all of the elements and limitations of independent claim 1, and claims 33-38 incorporate all of the elements and limitations of independent claim 32, and therefore are allowable for at least the same reasons. Applicant respectfully requests withdrawal of the §103 rejections over the respective combinations of Martinez, Rosenthal and Sawhney.

New Claims

Applicant submits that newly added claims 41-42 find support in the specification, as originally filed, and are patentable over the cited prior art for at least the same reasons as independent claims 1 and 32 from which they depend are patentable over the cited prior art.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests a notice of allowance. If there are any questions concerning this amendment and response, please contact the undersigned at the number below.

Respectfully submitted,
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